IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

MELISSA GLOBETTI and MARK GLOBETTI,	)	
Plaintiffs,	)	
vs.	)	Case No. CV-98-TMP-2649-S
SANDOZ PHARMACEUTICALS, CORPORATION,	)	
Defendant.	)	

MEMORANDUM OPINION

Before the court is the defendant's[1] motion for partial summary judgment on fraud and negligent misrepresentation, and a separate motion for partial summary judgment on warning claims, both filed July 15, 1999, on which the court conducted a hearing in December 2000. The parties have filed extensive briefs and voluminous exhibits dealing with the issues of (1) which state law applies to plaintiffs' tort claims, (2) whether Sandoz fraudulently misrepresented the potential hazards of Parlodel,[2] and (3) whether

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[1] Although identified in the style of the case as Sandoz Pharmaceuticals Corporation, the defendant has since changed its name to Novartis Pharmaceuticals Corporation. The defendant will be referred to herein as "Sandoz."

[2] Parlodel is the trade name for a drug produced by Sandoz which was, at the time plaintiff Melissa Globetti gave birth, prescribed to suppress lactation.

Sandoz adequately warned the plaintiffs of the potential hazards of Parlodel. After hearing the argument of counsel for both parties, and having reviewed the briefs and evidence, including supplemental filings by both parties, the court concludes that Alabama law governs the plaintiffs' claims. The court further concludes that the plaintiffs have set forth sufficient evidence to create a genuine issue of material fact as to their claims of fraud and failure to warn. As to plaintiffs' claim asserting strict liability, however, the defendant correctly notes that Alabama law does not provide such remedy. Consequently, defendant's motions for partial summary judgment on the issues of fraud, negligent misrepresentation, and failure to warn are due to be denied, and defendant's motion as to the claims asserting strict liability is due to be granted.

I. UNDISPUTED FACTS

Sandoz is a pharmaceuticals company that produced Parlodel, a prescription drug manufactured and sold in the United States and other countries. Sandoz produces the drug in New Jersey, where its headquarters are located. Chemically, Parlodel is bromocriptine mesylate, an ergot alkaloid with an added bromine atom.

Beginning in 1978, Parlodel was marketed in the United States for the treatment of menorrhea (the absence of menses) and galactorrhea (spontaneous lactation). Parlodel was approved by the Food and Drug Administration ("FDA") for prevention of physiological lactation ("PPL") from 1980 until January of 1995. Beginning in 1980, Sandoz began to aggressively market Parlodel to obstetricians for routine PPL use. Sandoz specifically aimed to get Parlodel placed on the standing orders of obstetricians, noting that it would then be prescribed for all non-breast-feeding postpartum patients.

Even before the drug was marketed in the United States, Sandoz-Basle (apparently an affiliated or parent company located in Switzerland) had collected reports of serious adverse drug reactions ("ADRs") connected to Parlodel. Included in the list of ADRs were "vasospastic reactions." No later than April of 1984, Sandoz had received "a sufficient number" of reports of seizures in patients given Parlodel for PPL to opine that there may be a "true association" between the drug and seizures. Sandoz recognized, years before the drug was approved for PPL use, that Parlodel could cause both vasodilation (the dilation of blood vessels) and vasoconstriction (the constriction of blood vessels). In spite of this knowledge, Sandoz took the position publically that Parolodel

could cause hypotension, but not hypertension. Vasoconstriction, when it occurs in the brain, can cause stroke. When it occurs in the heart, it can cause a heart attack, more specifically known as a myocardial infarction ("MI").[3]

After the FDA received numerous reports of seizures in patients given Parlodel for PPL, and after Sandoz had admitted that the seizure cases "were probably related to episodes of hypertension, which we know can occur under Parlodel," the FDA requested that Sandoz include reports of hypertension, "convulsive activity," and stroke under the "Adverse Reactions" section of its package insert. Although Sandoz had admitted internally that Parlodel could cause hypertension and seizures, it opposed inclusion of the reports as adverse reactions, and took the position with the FDA that such events were not caused by Parlodel.

The FDA in 1983 advised Sandoz that, pursuant to 21 C.F.R. 201.5(e), the package insert should be revised to include new warnings "as soon as there is reasonable evidence of an association of a serious hazard," even when causation has not been proven. The FDA also requested a revision of Parlodel's package insert to reflect a more serious warning. Sandoz included the revised

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[3] The plaintiff has offered expert testimony to support its conclusion that vasospasm, which is commonly known as ergotism, can cause both MIs and strokes.

warnings beginning in March of 1984, and continued to aggressively market Parlodel, instructing its sales force to "[b]e sure that Parlodel usage is not discontinued due to adverse experiences," and to "convert users of estrogen and on-treaters of PPL to Parlodel thereapy." While internally reporting that there "may be a true association" between Parlodel use and hypertension, seizures, or stroke in postpartum women taking Parlodel for lactation suppression, the sales force was told that such adverse events were not "necessarily related" to Parlodel, and were told that hypertension has "never before" been linked to Parlodel. On at least one occasion in 1984, the FDA deemed Sandoz's advertisements in the "Obstetrics and Gynecology" journal, ads directed toward the physicians who prescribe Parlodel, to contain at least three false statements, and to be generally "false and/or misleading."

The FDA in 1985 requested that certain "contraindications" be added to the Parlodel package insert to inform physicians that the drug was not approved for use in certain situations, *i.e.*, when a patient has suffered from hypertension or toxemia during pregnancy, or has received other ergot alkaloid drugs after delivery.[4] In spite of the FDA request, Sandoz continued to market Parlodel for

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[4] Apparently, other ergots produced by Sandoz, methergine and caffergot, were commonly used during delivery to prevent hemorrhaging.

routine use, seeking to "preserve" and "expand" the PPL business. Sandoz sales representatives were instructed to continue to push doctors to include Parlodel on their standing orders, providing medication order cards for use in hospitals that would order Parlodel for "all" non-breast-feeding patients.

Throughout the 1980s, Sandoz and the FDA continued to receive reports of adverse experiences, including hypertension, cardiac arrest, and stroke. In 1981, Sandoz completed a study, required by the FDA, known as "Study 60." In Study 60, Sandoz researchers concluded that hypertension could be caused by Parlodel, but Sandoz never submitted Study 60 to the FDA, despite repeated requests, until after Parlodel was withdrawn from the PPL market almost 15 years after the study was completed. In the late 1980s, the FDA persisted in its efforts to get Sandoz to revise its package insert and to send "Dear Doctor" letters[5] advising of the revisions. Apparently, in spite of Sandoz's alleged multiple mailings, a majority of the practicing obstetricians to whom the letters were aimed never received the letters.

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[5] Such mass mailings are a common method by which pharmaceuticals companies provide information directly to the prescribing physicians in order to draw their attention to any labeling updates or changes in the product.

Reports of other serious adverse reactions continued to be received by Sandoz in 1987 concerning stroke and postpartum myocardial infarctions. In 1988, an FDA advisory committee recommended that Parlodel not be used "routinely," but be limited to women with "specific indications," such as those who deliver stillborns. Even so, Sandoz continued to market Parlodel aggressively for PPL and did nothing to advise doctors who had Parlodel on standing order to change their routine use of the drug.

In 1989, the FDA requested that Sandoz voluntarily withdraw Parlodel from the market for PPL use. Sandoz declined, and continued to promote the sale of Parlodel, stressing both the "safety" and "efficacy" of Parlodel in spite of its own studies that demonstrated a "substantial positive association" between Parlodel and seizures and "an extremely strong positive association" between Parlodel and seizures in women who had received other ergots after delivery.

In 1994, the FDA notified Sandoz that it would hold a hearing on the withdrawal of Parlodel for prevention of postpartum lactation. Sandoz continued to maintain publicly that Parlodel was "safe." On January 17, 1995, the FDA withdrew Parlodel from the market for inhibiting postpartum lactation.

During the time Parlodel was prescribed routinely for postpartum lactation suppression, Sandoz, in accordance with federal regulations, distributed the drug with a package insert that contained information about the drug. The language in that package insert was approved by the FDA. The language of the package insert in effect at the time the drug was prescribed to Melissa Globetti, which also was published in the Physician's Desk Reference, states:

WARNINGS

Fifteen cases of stroke during Parlodel (bromocriptine mesylate) therapy have been reported mostly in postpartum partients whose prenatal and obstetric courses has been uncomplicated. Many of these patients experiencing seizures and/or strokes reported developing a constant and often progressively severe headache hours to days prior to the acute event. Some cases of strokes and seizures during therapy with Parlodel (bromocriptine mesylate) were also preceded by visual disturbances (blurred vision, and transient cortical blindness). Four cases of acute myocardial infarction have been reported, including 3 cases receiving Parlodel (bromocriptine mesylate) for the prevention of physiological lactation. The relationship of these adverse reactions to Parlodel (bromocriptine mesylate) administration is not certain.

...

ADVERSE REACTIONS

...

Physiological Lactation

...Serious adverse reactions include 38 cases of seizures(including 4 cases of status epilepticus), 15 cases of stroke, and 3 cases of myocardial infarction

> **among postpartum patients. Seizure cases were not necessarily accompanied by the development of hypertension. An unremitting and often progressively severe headache, sometimes accompanied by visual disturbance, often preceded by hours to days many cases of seizure and/or stroke. Most patients had shown no evidence of toxemia during the pregnancy.**

The package insert underreported the number of MIs that had been reported to be caused by Parlodel. By 1995, Sandoz had received more than 20 reports of Parlodel-linked MIs, including 12 in women who were taking the drug for PPL. Similarly, Sandoz reported far fewer incidents of stroke and seizure than it knew had occurred. According to plaintiff's expert witness Martha Bennett, Sandoz violated FDA regulations by failing to submit to the FDA "a large number of reports of adverse reactions associated with the use of Parlodel."[6]

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[6] In conjunction with its motion for partial summary judgment on the fraud claims, the defendant has moved to strike the testimony of Ms. Bennett on Daubert grounds. The court concludes that the motion is without merit for at least two reasons. First, the court notes that Ms. Bennett's opinion testimony is not the type of scientific or technical testimony for which Daubert sets the standard. Ms. Bennett is more akin to an "industry standard" expert who speaks from work experience in a particular field - her experience arising from more than a decade of employment with the FDA, where she worked in the field of compliance. Second, even under a Daubert analysis Ms. Bennett would be qualified to render an opinion as to whether ADRs were properly reported to the FDA by Sandoz because she worked in that field for many years and was trained by the FDA to make such assessments. Accordingly, the motion as it relates to Ms. Bennett is due to be denied.

In 1993, plaintiff Melissa Globetti, an Alabama resident, was 33 years old and pregnant with her sixth child. Her health was good. She had no known risk factors for coronary disease; she had no family history of heart disease, was not a smoker, was not overweight, was relatively young, and had very low (indeed, "protective") cholesterol levels. During neither the pregnancy nor the delivery did she experience any hypertension, and she had no history of high blood pressure. During her pregnancy and after giving birth, Ms. Globetti was treated by Dr. Jeffers Fowlkes, who is licensed to practice in obstetrics and gynecology and who is a fellow of ACOG. Ms. Globetti gave birth to her child at St. Vincent's Hospital in Birmingham, Alabama. After the birth she decided not to breast-feed. Pursuant to Dr. Fowlkes' standing order for non-breast-feeding mothers, she was given 2.5 mg of Parlodel, twice daily for fourteen days, to suppress lactation. Mrs. Globetti had taken Parlodel before in connection with some or all of her prior deliveries.

On the fifth or sixth day after delivery, Mrs. Globetti began to experience chest pain and was rushed to the emergency room of the local hospital in Talladega, Alabama. Doctors determined that she had suffered an acute myocardial infarction ("MI") of the anterior wall of her left ventricle. Her initial cardiologist, Dr.

Watford, concluded that it had been caused by a spasm of the coronary artery. After learning of Ms. Globetti's MI, Dr. Fowlkes and the other obstetricians in his practice group removed Parlodel from standing order and stopped prescribing the drug for postpartum lactation suppression.

Dr. Fowlkes does not recall ever receiving or seeing copies of the two "Dear Doctor" letters that Sandoz claims it sent advising him of a change in the package insert. Sandoz admits that from the time the package insert was developed in 1987 until after Ms. Globetti received Parlodel, the number of "adverse events" listed in the package insert and PDR was not changed, even though Sandoz received more reports of adverse events, including reports of myocardial infarction. Dr. Fowlkes testified that, because the number of myocardial infarctions revealed in the package insert and PDR were low and because the number did not change from 1987 to 1993, he would conclude that Parlodel did not cause MIs.

Dr. Fowlkes does not recall specifically how he obtained information regarding the potential hazards of Parlodel. He has stated that he "most likely" was called on by a Sandoz sales rep, and then read the PDR when he first started prescribing Parlodel in the early 1980s. He recalls two of Sandoz's drug reps, Noel Keith Sellers and Bo Trammell, but does not recall any specific

representations made to him by any Sandoz representative. When Dr. Fowlkes prescribed Parlodel to Ms. Globetti, he was aware of some risk of stroke, seizure, and hypertension associated with the drug. He stated, however, that Sandoz's inclusion of the statement that "relationship of these adverse reactions to Parlodel ... is not certain" indicated to him that the adverse reaction was not related to the drug and that the patient need not be warned of that hazard.

Dr. Fowlkes does not recall ever being informed by Sandoz that the FDA had requested the voluntary withdrawal of Parlodel from the market in 1989, or that Parlodel was no longer accepted for "routine" use, or that Parlodel users should have their blood pressure monitored even after they leave the hospital. Dr. Fowlkes did testify that the need for blood-pressure monitoring after release from the hospital would have been a factor that probably would have led him to stop prescribing it. Dr. Fowlkes also has testified that the numbers of cases of stroke, hypertension, and myocardial infarction reported by Sandoz in its package insert and the PDR were not accurate or up-to-date. Dr. Fowlkes has testified that if he had been apprised of the actual risks posed by Parlodel he would have weighed the risk posed by the medicine to the benefit and, where the risk outweighed the benefit, he would not have prescribed it.

The defendant argues in support of its motions for partial summary judgment that, in the absence of testimony establishing a misrepresentation by Sandoz to Ms. Globetti, plaintiffs' cause of action for fraud under Alabama law fails, and defendant is entitled to entry of summary judgment in its favor. Defendant further argues that the plaintiffs' failure-to-warn claims also are due to be dismissed because the defendant discharged its duty to warn by providing the package insert information, and because the decision to take Parlodel was not made by the plaintiffs, but by a "learned intermediary," Dr. Fowlkes.

The plaintiffs counter that a fraud claim is viable even absent a direct representation to the plaintiffs, and that Sandoz is liable for failing to adequately warn the plaintiff of the hazards related to the use of Parlodel to inhibit postpartum lactation. In essence, plaintiffs argue that the Globettis are entitled to recover for misrepresentations or suppressions made to the FDA and/or Dr. Fowlkes.

II. CHOICE OF LAW

This action was first filed in New York. Consequently, the court must first look to New York law to determine which state law applies to plaintiffs' claims. Under New York law, the "law of the

jurisdiction with the most significant interest in, or relationship to, the dispute" will govern. Brink's Ltd. v. South African Airways, 93 F.3d 1030, 1033 (2d Cir. 1996). Looking at the relationship between the parties and the states involved, the court notes that: (1) the plaintiffs are Alabama residents, (2) the injuries complained of occurred in Alabama, (3) the defendant has its principal place of business in New Jersey; (4) the drug that allegedly caused the injury was manufactured in New Jersey, (5) the defendant does business in Alabama, (6) the drug was prescribed in Alabama by a physician licensed in Alabama, (7) the plaintiff ingested the drug in Alabama, (8) the warnings at issue were created in New Jersey, (9) the warnings were provided to doctors and hospitals in Alabama; and (10) the sales representatives who allegedly misrepresented or suppressed facts from Dr. Fowlkes made their representations in Alabama.

The plaintiffs argue that New Jersey law should apply because New Jersey's interest in regulating the conduct of a company located within its borders outweighs Alabama's interest in seeing that its citizens are compensated for their damages. The defendant asserts that Alabama law applies. Having considered the argument of the plaintiffs and having reviewed the applicable law, the court finds that Alabama's interest in this litigation outweighs New

Jersey's interest. The court rejects plaintiffs' notion that Alabama "has no interest in having a pharmaceutical manufacturer in New Jersey comply with ... Alabama's negligence standards." (Plaintiff's brief in opposition, p. 70.) To the contrary, because the plaintiffs reside in Alabama, the drug was prescribed in Alabama, the injury occurred in Alabama, and the allegedly fraudulent marketing efforts were directed toward Alabama doctors, the court finds that Alabama has a superior interest in having its substantive law apply to this case.

III. SUMMARY JUDGMENT STANDARD

Under Federal Rule of Civil Procedure 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The party seeking summary judgment "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of

a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)(quoting Fed. R. Civ. P. 56(c)). The movant can meet this burden by presenting evidence showing there is no dispute of material fact, or by showing that the nonmoving party has failed to present evidence in support of some element of its case on which it bears the ultimate burden of proof. Celotex, 477 U.S. at 322-23. There is no requirement, however, "that the moving party support its motion with affidavits or other similar materials *negating* the opponent's claim." Id. at 323.

Once the moving party has met his burden, Rule 56(e) "requires the nonmoving party to go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions of file,' designate 'specific facts showing that there is a genuine issue for trial.'" Id. at 324 (quoting Fed. R. Civ. P. 56(e)). When the nonmoving party does not respond, "summary judgment, if appropriate, shall be entered against the adverse party." Fed. R. Civ. P. 56(e).

The nonmoving party may not merely rest on her pleadings. Celotex, 477 U.S. at 324. "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element

essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322.

After the plaintiff has had the opportunity to respond to a proper motion for summary judgment, the court must grant the motion if there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The substantive law will identify which facts are material and which are irrelevant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. at 248. "[T]he judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 249. His guide is the same standard necessary to direct a verdict: "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52; see also Bill Johnson's Restaurants, Inc. v. N.L.R.B., 461 U.S. 731, 745 n.11 (1983). However, the nonmoving party "must do more than show that there is some metaphysical doubt as to the material facts. "Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). If the evidence is merely colorable, or is not

significantly probative, summary judgment may be granted. Anderson, 477 U.S. at 249 (citations omitted); accord Spence v. Zimmerman, 873 F.2d 256 (11th Cir. 1989). Furthermore, the court must "view the evidence presented through the prism of the substantive evidentiary burden," so there must be sufficient evidence on which the jury could reasonably find for the plaintiff. Anderson, 477 U.S. at 254; Cottle v. Storer Communication, Inc., 849 F.2d 570, 575 (11th Cir. 1988). Nevertheless, credibility determinations, the weighing of evidence, and the drawing of inferences from the facts are the function of the jury, and therefore the evidence of the non-movant is to be believed and all justifiable inferences are to be drawn in his favor. Anderson, 477 U.S. at 255. The non-movant need not be given the benefit of every inference but only of every reasonable inference. Brown v. City of Clewiston, 848 F.2d 1534, 1540 n.12 (11th Cir. 1988).

IV. FRAUD

The defendant seeks summary judgment on all of plaintiffs' claims based on fraud[7] on the basis that plaintiff has failed to

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[7] Plaintiffs assert claims for fraud, negligent misrepresentation, and suppression, all of which are viable claims under Alabama law. See Alabama Code §§ 6-5-100 through 104. The fraud claims will be treated jointly herein.

come forward with evidence sufficient to withstand summary judgment on the issue of whether: (1) Sandoz made any false representations or suppressions of material fact to Ms. Globetti, her doctors, the FDA, or the public; (2) any alleged misrepresentation or concealment induced Ms. Globetti to take, or her doctor to prescribe, Parlodel; and (3) the alleged fraud caused her injury.

To survive summary judgment on the active fraud claims, plaintiffs must show that the defendant made "(1) a false representation, (2) of an existing material fact, (3) that is reasonably relied upon, and (4) damage resulting as a proximate cause." Wheelan v. Sessions, 50 F. Supp. 2d 1168, 1172 (M.D. Ala. 1999). To survive summary judgment on the concealment claims, the plaintiffs must demonstrate that the defendant suppressed a material fact, having had a duty to communicate that fact, and that the injury resulted from the suppression. Doss v. Serra Chevrolet Inc., ___ So. 2d ___, 2000 WL 1520302 (Ala. Civ. App., Oct. 13, 2000).

A. The Plaintiff's Standing to Sue

The defendant first asserts, and the plaintiffs agree, that no misrepresentation was made to the plaintiffs. While it is generally true that a third party to a misrepresentation has no

cause of action for fraud, the Alabama Supreme Court has recognized that "it is not always necessary to prove that a misrepresentation was made directly to the person who claims to have been injured." Wheelan, 50 F. Supp. at 1174, quoting Thomas v. Halstead, 605 So. 2d 1181, 1184 (Ala. 1992). In spite of the general rule that a stranger to a transaction has no cause of action for fraud, there is an exception. "[I]f a third person is injured by the deceit, he may recover against the one who made possible the damages to him by practicing the deceit in the first place." Wheelan, 50 F. Supp. 2d at 1174, quoting 37 C.J.S. Fraud § 60 at 344. It then follows that there exists a duty "not to make a false representation to those to whom a defendant intends, for his own purposes, to reach and influence by the representation." Wheelan, 50 F. Supp. 2d at 1174, quoting Colonial Bank of Ala. v. Ridley & Schweigert, 551 So. 2d 390, 396 (Ala. 1989).

In the instant case, the fraudulent representations that plaintiffs allege were made not to the plaintiffs but to the FDA and/or to Dr. Fowlkes. The party injured by this alleged deceit, however, clearly is Melissa Globetti. Furthermore, it is clear that Sandoz, for its own purposes of promoting its product and making a profit, intended to reach and influence the patients of obstetricians, such as Ms. Globetti. Sandoz wanted to promote its

product as safe and effective so that obstetricians would prescribe the drug to its patients. Consequently, the court finds that the plaintiffs have a cause of action for the alleged fraud, even absent any direct representations by Sandoz to Ms. Globetti.

B. Falsity

To be actionable as active fraud, the representations made by Sandoz in the package insert or the sales pitches to doctors, (or both), must be shown to be false. In this case, the defendant admits that the package insert at issue asserted that four cases of "acute myocardial infarction have been reported," including three in which the patient had received Parlodel for suppression of postpartum lactation. The plantiffs have produced evidence which, if believed, would indicate that the defendant knew of many more such events. The defendant admits that its Parlodel package insert also states that: "The relationship of these adverse reactions to Parlodel (bromocriptine mesylate) administration is not certain." The plaintiffs have produced evidence from which a reasonable jury could infer that Sandoz knew of a causal relationship between its drug and vasoconstrictive reactions such as MIs. The plaintiffs also have produced evidence that, even after the FDA instructed the defendant that Parlodel should not be used in routine cases of

postpartum lactation suppression, the defendant continued to market the drug to doctors as a drug that should be placed on standing order. Construing the facts of the instant case in the light most favorable to the plaintiffs, the court concludes that a reasonable jury could find that representations made by the defendant to Dr. Fowlkes about the safety of Parlodel[8] could be found to be false. Accordingly, the first element of active fraud is met.

C. Concealment

To be actionable as concealment, the plaintiffs must demonstrate that the defendant suppressed a material fact that it had a duty to disclose. Evidence relating to this element goes hand in hand with the evidence of falsity. Plaintiffs have set forth evidence to support their claim that the number of MIs reported on the package insert and to the FDA were false, and also that Sandoz knew of other cases and suppressed them. Similarly, the plaintiffs have produced evidence from which a jury could

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[8] The defendant further argues that the facts allegedly misrepresented were not material. The court rejects this argument in light of Dr. Fowlkes' testimony that he felt the low numbers of MIs reported indicated a lack of causation. Consequently, it is reasonable to expect that a higher number of such reactions might have led Dr. Fowlkes to question whether Parlodel caused myocardial infarctions in postpartum women and might have alerted him to the need to remove Parlodel from his standing order.

conclude that Sandoz suppressed its own conclusions about the hazards of Parlodel, for example, by failing to disclose Study 60 to the FDA. Accordingly, the court finds that the plaintiffs have met their burden of showing that the defendant concealed material facts about the safety of Parlodel.

The question of whether Sandoz had a duty to disclose such information is an even simpler one. Under Alabama law, the failure to tell the whole truth, or to provide only partially correct information, may constitute fraudulent concealment. See Cunningham v. H.A.S. Inc., 74 F. Supp. 2d 1157, 1162 n.6 (M.D. Ala. 1999). In fact, Alabama courts have held that:

> To tell half a truth has been declared to be equivalent to the concealment of the other half. A partial and fragmentary disclosure, accompanied by the willful concealment of material and qualifying facts is not a true statement, and is as much a fraud as an actual misrepresentation, which, in effect, it is. Therefore, if one willfully conceals and suppresses such facts, and thereby leads the other party to believe that the matters to which the statements made relate are different from what they actually are, he is guilty of a fraudulent concealment.

Gold Kist, Inc. v. Brown, 495 So. 2d 540 (Ala. 1986), quoting Jackson Co. v. Faulkner, 315 So. 2d 591 (Ala. Civ. App. 1975). Furthermore, it has been noted that even though one may not have a duty to disclose certain facts, if he "undertakes to do so, either

voluntarily or in response to inquiries, he is bound not only to state truly what he tells, but also not to suppress or conceal any facts within his knowledge which will materially qualify those stated." Jackson, 315 So. 2d at 600. Accordingly, in this case, a duty arose when Sandoz undertook to disclose information about the safety of Parlodel.

The existence of a duty may arise in other ways, as well. Alabama law requires an assessment of a number of factors, including: (1) the relationship among the parties; (2) the relative knowledge of the parties; (3) the value of a particular fact; (4) the customs of the trade; and (5) other relevant circumstances. Cunningham, 74 F. Supp. 2d at 1163. In this case, Sandoz had a duty under federal law to disclose certain reports of adverse reactions to the FDA and, thereby, to doctors and patients.[9] Sandoz's level of knowledge as to the effects of Parlodel clearly was superior to either that of the FDA or any individual doctor. The value of the fact that Parlodel might cause myocardial infarction was clearly paramount under circumstances such as Ms.

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[9] The plaintiffs have not addressed directly the "customs" of the pharmaceuticals industry, but the evidence submitted regarding FDA regulations makes clear that pharmaceuticals companies customarily (and by law) disclose information about the safety of their products to the FDA.

Globetti's, where the plaintiff had no medical need for the drug, but was taking it solely for PPL.

Consequently, Sandoz had a duty to disclose to the FDA and doctors information about the safety of Parlodel. As discussed in Section III C *supra*, a reasonable juror could conclude that, in reporting four incidents of myocardial infaction to the FDA, Sandoz concealed the other 16 MIs that it knew had occurred. Finally, the "relevant circumstances" of this case weigh in favor of finding that Sandoz had a duty to disclose the true hazards of Parlodel. Sandoz knew of, and had promoted, the routine use of Parlodel in postpartum women even after the FDA rejected such use and even knowing that doctors were not monitoring the blood pressure of these women after they were discharged from the hospital. Considering all of the factors and "relevant circumstances" as required by Alabama law, the court finds that Sandoz had a duty to disclose to the FDA and prescribing doctors the known hazards of ingesting its drug.

D. Reasonable Reliance

The defendant argues that the plaintiffs must have "justifiably relied" upon the alleged misrepresentations. (Defendant's brief, p. 23). The law in Alabama, however, now

requires a lesser standard of reliance, deemed "reasonable reliance." See Foremost Ins. Co. v. Parham, 693 So. 2d 409, 423 (Ala. 1997)(adopting reasonable reliance standard and rejecting the justifiable reliance standard set forth in prior cases). Under the applicable standard, the reliance need only have been "reasonable under the circumstances." Wheelan, 50 F. Supp. 2d at 1173. In this case, Dr. Fowlkes asserted that he would have spoken with Sandoz's sales reps and read the information in the PDR at some time before prescribing Parlodel for Ms. Globetti. Certainly, defendant cannot argue that it is unreasonable for a doctor to rely on the PDR in making prescribing decisions.[10] Likewise, Ms. Globetti clearly relied upon her doctor in taking the Parlodel that he prescribed. Her actions also cannot be deemed less than

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[10] Sandoz would have the court believe that there is no evidence that Dr. Fowlkes relied upon any representations by Sandoz because he cannot specifically remember reading the PDR and cannot specifically remember any statements made by any Sandoz representative. The court finds this argument unpersuasive in light of the doctor's testimony that his habit is to listen to the sales pitches of the drug representatives, and to read the PDR. Furthermore, if Dr. Fowlkes' reliance on the PDR was "unreasonable," then Ms. Globetti - like most every patient who has ever received a prescription from a doctor - would have a cause of action for medical malpractice, and doctors would be required to conduct their own research into a drug before being able to prescribe it.

reasonable. Consequently, the plaintiffs have met their burden of showing the second element of fraud.[11]

E. Damages

The final element the plaintiffs must prove is that Ms. Globetti was damaged by the defendant's actions in misrepresenting or concealing the potential hazards of the drug. The fact that Ms. Globetti was injured is not in dispute. Defendant does, however, dispute that the plaintiffs can show any causative link between the alleged fraud and the injury. This element has been dealt with in detail in this court's Order denying summary judgment on the issue of medical causation, and need not be repeated here. Suffice it to say that the plaintiffs have set forth sufficient evidence to maintain their action for fraud.

The court finds that, construing the facts in the light most favorable to the plaintiffs as the court must, a reasonable jury

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[11] Defendant has asserted that Alabama has rejected a "fraud on the market" theory, citing, *i.e.*, Ex parte Household Retail Services, Inc., 744 So. 2d 871 (Ala. 1999). In that case, and others cited by Sandoz, the issue was whether class certification of fraud and suppression claims would be proper in the absence of evidence that any plaintiff relied on any representations or suppressions made by the defendant. That issue is not sufficiently similar to the case at hand and simply stands for the proposition that reliance, under Alabama fraud law, must be proven in each circumstance and may not be presumed. Id. at 880-81.

could find that Sandoz made misrepresentations to Dr. Fowlkes, and that Sandoz concealed from the FDA and Dr. Fowlkes information about the potential hazards of Parlodel. Accordingly, the defendant's motions for partial summary judgment on the claims of fraud, negligent misrepresentation, and suppression are due to be denied.

V. WARNING CLAIMS

The plaintiffs have asserted claims based on theories that the defendant failed to warn the plaintiffs, the FDA, or their doctor about the hazards of Parlodel. Plaintiff's first claim based on a failure-to-warn theory is set forth as a strict liability claim (Count One). Such a claim is not viable under Alabama law, where the Alabama Supreme Court has specifically retained concepts of negligence in products liability cases and has rejected notions of any no-fault liability. See Griggs v. Combe Inc., 456 So. 2d 790, 792 (Ala. 1984), citing Casrell v. Altec Industries, 335 So. 2d 128, 132 (Ala. 1976), and Atkins v. American Motors Corp., 335 So. 3d 134, 139 (Ala. 1976). Consequently, defendant's motion for partial summary judgment as to Count One is due to be granted.

The plaintiff has set forth additional warning claims, asserting that Sandoz was negligent in failing to warn of the real

risks of Parlodel in postpartum women and that Parlodel is an "unreasonably dangerous" product for which plaintiffs are entitled to relief under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD").[12] The elements to be proved in a negligence case in Alabama are that the defendant had a duty, breached its duty, and proximately caused harm to the plaintiff. Under the AEMLD, the plaintiff similarly must provide evidence of negligence by showing that the defendant failed to provide adequate warnings of the hazards of Parlodel. See Stone v. Smith, Kline & French Labs., 447 So. 2d 1301, 1303-04 (Ala. 1984).[13] The defendant has moved for partial summary judgment on plaintiffs' failure-to-warn claims on the basis that these are barred by Alabama's learned intermediary doctrine.

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[12] The defendant also asserts that plaintiffs' claims for breach of implied and express warranties (Counts Three and Four), and for punitive damages (Count Nine), also are claims based on warning theories. The court, however, finds that those claims, while they may involve questions as to the conduct of Sandoz in developing the warnings, are not governed by a failure-to-warn theory and are not due to be discussed herein. Accordingly, to the extent that the defendant has moved for summary judgment on Counts Three, Four, and Nine, the motion is due to be denied.

[13] The Alabama Supreme Court in Stone noted that Alabama imposes liability for pharmaceuticals companies in the production of prescription drugs pursuant to Comment k to Section 402A of the Restatement (Second) of Torts (1965), which "does no more than codify the principles of negligence." Stone, 447 So. 2d at 1303.

It is well settled in Alabama that, in cases involving pharmaceutical companies selling prescription drugs, the learned intermediary doctrine applies. See, e.g., Stone v. Smith, Kline & French Labs., 731 F.2d 1575, 1579-80 (11th Cir. 1984). Under Alabama law, "a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product." Toole v. Baxter Healthcare Corp., ___ F.3d ___, 2000 WL 1839209 (11th Cir. Dec. 14, 2000). The doctrine provides a limited exception to the general rule that the manufacturer must warn the "foreseeable user," (in this case the ultimate consumer, Ms. Globetti), of the hazards posed by its product. Id.

The fact that some warning is given to the doctor, however, is not dispositive of the failure-to-warn issue. Where a warning has been provided, a question arises as to whether the warning was adequate, and adequacy of the warning is a question of fact for the jury. See Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993).[14]

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[14] Sandoz argues that summary judgment on the warning claims is due to be granted because the plaintiffs have failed to present expert medical testimony regarding the inadequacy of the warning. However, Sandoz fails to city any authority for such a requirement under Alabama law, and the court finds none.

In this case, the plaintiffs assert that the warning provided by Sandoz was inadequate both because it did not fully disclose all the reports of adverse reactions to the drug of which Sandoz was aware, and because the warning failed to acknowledge any causal link between the drug and myocardial infarction or other vasocontrictive events, even though Sandoz medical officials had evidence to reasonably believe that Parlodel could cause such reactions. That knowledge, plaintiffs assert, suggests that Sandoz acted negligently, wantonly, or willfully in failing to adequately warn of the potential hazards of Parlodel.

The defendant counters that the warning set forth in the package insert and in the Dear Doctor letters was approved by the FDA, and that the FDA at all times relevant to this lawsuit approved the use of Parlodel for suppression of postpartum lactation. While those facts are relevant to any evaluation of Sandoz's conduct, they are not dispositive in light of the fact that the plaintiffs argue, and support by admissible evidence, that Sandoz knew of increased risks of the drug and failed or refused to pass that information on to Ms. Globetti's learned intermediary, Dr. Fowlkes. Viewed in the light most favorable to the plaintiffs, Sandoz underreported the number of MIs to Dr. Fowlkes through the PDR and failed to send him the "Dear Doctor" letter that might have

given him some notice of an increased risk. Under Alabama law, a warning may be deemed inadequate if it "understate[s] the risks" of the drug. Toole, 999 F.2d at 1434.[15]

Dr. Fowlkes testified that the number of MIs reported was relevant to his assessment of any risk posed by Parlodel. Thus, a reasonable jury could determine that Dr. Fowlkes would not have prescribed Parlodel routinely for postpartum lactation suppression if he had known the actual numbers of MIs that had been reported.

It is clear that the evidence offered by the plaintiffs raises a question of material fact as to the adequacy of Sandoz's warning. Consequently, the plaintiffs have presented a *prima facie* case of negligence and a *prima facie* case under the AEMLD, and the defendant's motions for partial summary judgment on the warning claims set forth in Counts Two and Eight are due to be denied.

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[15] In Toole, the Eleventh Circuit Court of Appeals recognized that, even where a doctor is warned that there is some possibility of an adverse reaction - in that case that a silicone gel breast implant could rupture - that fact does not automatically render the warning adequate. That is because doctors also need to be aware of the frequency of such adverse reactions, because where the reactions may be a "very very unusual event" it poses less of a risk and thus affects the doctor's advice concerning use of the drug or device. Id. at 1433 and n. 6.

VI. CONCLUSION

The court finds that the plaintiffs have shown there to be triable issues of fraud, suppression, negligence, and failure to warn under the AEMLD. The defendant's motions for partial summary judgment on these claims is therefore due to be DENIED. The plaintiffs have failed to demonstrate that there is any genuine issue of material fact as to their claims based on strict liability, however, and the motion with respect to that claim is thus due to be GRANTED. A separate order will be entered contemporaneously herewith denying in part and granting in part the defendant's motions for partial summary judgment.

DONE this the 2nd day of February, 2001.

T. MICHAEL PUTNAM
CHIEF MAGISTRATE JUDGE